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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,314	10/24/2005	Atsushi Miyawaki	P26360	4623
7055 7590 07/13/2007 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			EXAMINER LEE, JAE W	
			ART UNIT 1656	PAPER NUMBER
			NOTIFICATION DATE 07/13/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
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<b>Office Action Summary</b>	Application No. 10/516,314	Applicant(s) MIYAWAKI ET AL.	
	Examiner Jae W. Lee, Ph.D.	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2, 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-7 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/17/2005, 07/25/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Application status***

The preliminary amendment, filed on 12/10/2004, is acknowledged, wherein Applicants have amended claims 3 and 6-10.

Claim(s) 1-10 is/are pending in this application.

### ***Priority***

A claim of priority to the 371 of PCT/JP03/07337, filed on 06/10/2003, and JAPAN 2002-168584, filed on 06/10/2002, is acknowledged.

### ***Election***

Applicant's election with traverse of Group II, Claims 3-7 and 10 is acknowledged. The traversal is on the ground(s) that a claimed DNA molecule encoding protein X, shares a corresponding technical feature with the protein X according to the PCT International Search and Examination Guidelines, Part III, Chapter 10, example 39.

In response to Applicant's traversal, the Examiner finds arguments not persuasive because as explained in the previous Office action, the technical feature is taught by the prior art as disclosed in the reference of Mizuno et al. (Biochemistry, 2001,40, pg. 2502-2510). The reference teaches a red fluorescent protein from Discosoma as a fusion tag and a partner for FRET, which corresponds to the invention

Art Unit: 1656

of Group I, in the recitation of "a chromoprotein having either one of the following amino acid sequences: (a) the amino acid sequence shown in SEQ ID NO: 1; and (b) an amino acid sequence comprising a deletion, substitution and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1, and having light-absorbing properties.," and thus, the shared technical feature of the groups I (a chromoprotein) and II (a DNA encoding a chromoprotein) is not a "special technical feature" even if the chromoprotein is encoded by the DNA. Therefore, unity of invention between the groups does not exist. The requirement is still deemed proper.

Claim(s) 1, 2, 8 and 9 is/are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate

paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Applicants' filing of information disclosures, filed on 03/17/2005 and 07/25/2006, is acknowledged. Those references considered have been initialed, while those missing references listed under IDS have been lined through.

### ***Objections to the Oath or Declaration***

A new oath or declaration is required because of following informalities. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: the title of the application is not "Chromoprotein."

### ***Claim Objections***

Claim(s) 3, 4, 6, 7 and 10 is/are objected to because of the following informalities:

Claims 3 and 10 are objected to because they depend from a non-elected claim, and also for containing non-elected subject matter.

Claim 4 (6 and 7 dependent therefrom) is objected to because the phrase, "one of followings," can be improved with respect to grammar. The Examiner suggests --- one of the following ---.

Appropriate correction is required.

***Claim Rejections - 35 U.S.C. § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3-5 and 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed product, as written, does not sufficiently distinguish over the naturally occurring product in living organisms, i.e., DNA of *Cnidopus japonicus*. In the absence of "the hand of man", the naturally occurring processes are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206, USPQ 193 (1980) and M.P.E.P. 2105.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-7 and 10 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to a genus of DNAs of either one of followings: (a) DNA encoding the amino acid sequence shown in SEQ ID NO: 1 and (b) any DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1, and having light-absorbing properties.

To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of [compositions or methods], it must be clear that: (1) the identifying characteristics of the claimed [compositions or methods] have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

The specification discloses an example of an isolated nucleic acid sequence comprising SEQ ID NO: 2 which encodes a chromoprotein from *Cnidopus japonicus*. However, this is an inadequate written description for a genus of DNAs of either one of followings: (a) DNA encoding the amino acid sequence shown in SEQ ID NO: 1 and (b) any DNA encoding an amino acid sequence which comprises a deletion, substitution

and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1, and having light-absorbing properties.

The specification does not provide a disclosure of any particular structure to function/activity relationship in *any* DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1. The specification also lacks description with respect to what function, if any, is required for *any* DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO:

1. Further, the specification fails to describe any identification of structural characteristics or properties of *any* DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1.

Given the lack of additional representatives of a genus of DNAs of either one of followings: (a) DNA encoding the amino acid sequence shown in SEQ ID NO: 1 and (b) any DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1, and having light-absorbing properties as encompassed by the claim, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.



Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

Claims 3-7 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because the specification, while being enabling for an isolated nucleic acid sequence comprising SEQ ID NO: 2 which encodes a chromoprotein from *Cnidopus japonicus*, does not reasonably provide enablement for any DNA of either one of the followings: (a) DNA encoding the amino acid sequence shown in SEQ ID NO: 1 and (b) any DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1, and having light-absorbing properties. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to

make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

Claims 3-7 and 10 are so broad as to encompass any DNA of either one of followings: (a) DNA encoding the amino acid sequence shown in SEQ ID NO: 1 and (b) any DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1, and having light-absorbing properties.

The claims rejected under this section of U.S.C. 112, first paragraph, do not place any structural limits on the "any DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1." Since the nucleic acids encoding a polypeptide determines its structural and functional properties, predictability of which nucleic acid sequence can be used while obtaining the desired function in the encoded protein requires a knowledge of and guidance with regard to which nucleic acids and amino acids of the polypeptide's sequence, if any, are conserved (i.e.

Art Unit: 1656

expectedly intolerant to modification), and detailed knowledge of the ways in which the nucleic acid sequence and its encoded polypeptide's structure relates to its desired function. In addition, the scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of different DNA sequences and encoded polypeptides.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

With regard to Claim 7, previous studies demonstrate that the transformation of plants or the gene transfer to plants have been difficult with low success rate (Potrykus, *Biotechnology* 8(6): 535-542). Further, a "transformant" reads on animal and plant organisms, respectively. In this regard, the specification fails to disclose representative examples of successful transformants using any animal or plant with the claimed DNAs. Thus, Applicants have not provided sufficient guidance to make such.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one or several

Art Unit: 1656

amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1 because the specification does not establish: (A) regions of any DNA structure which may be modified without affecting the desired biological activity, i.e., the ability to fluorescence at certain wavelength; (B) the general tolerance of any DNA to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleic acid residue with an expectation of obtaining the desired biological function in the encoded polypeptide; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Because of this lack of guidance, and the fact that the relationship between the polynucleotide sequence and the encoded proteins' activity/function is not well understood and unpredictable (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to make and use the claimed invention.

The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1 while having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wall et al. (The structural basis for red fluorescence in the tetrameric GFP homolog DsRed, *Nature Structural Biology*, 2000, 7(12): 1133-1138).

The instant claims are drawn to a DNA of either one of followings: (a) DNA encoding the amino acid sequence shown in SEQ ID NO: 1 and (b) DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1, and having light-absorbing properties.

The reference of Wall et al. teaches the structural basis for red fluorescence in the tetrameric GFP homolog DsRed. The reference specifically teaches a DNA encoding a red fluorescence protein, DsRed, which reads on the recitation, "DNA encoding an amino acid sequence which comprises a deletion, substitution and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1," of Claim 4, and the recitation, "a nucleotide sequence comprising a deletion, substitution and/or addition of one or several amino acids with respect to the

nucleotide sequence shown in SEQ ID NO: 2," of Claim 5. It is noted by the Examiner that all DNA and polypeptide molecules have light-absorbing properties. The reference also teaches making a transformant, i.e., JM109 (DE3) cells, comprising the DNA sequence inserted in the recombinant vector, pRSET<sub>B</sub>, which encodes said DsRed protein (see pg. 1137, right column, under "Protein purification and crystallization).

Claim 3 is included in this rejection for the following reasons. Although said DsRed protein has the following properties:  $\lambda_{\text{max,absorbance}} = 558 \text{ nm}$ , and  $\lambda_{\text{max,emission}} = 583 \text{ nm}$  (see pg. 1134, left column, line 11), which is -1 nm from the claimed 559 nm absorbance wavelength, and +5 nm from the claimed 578 nm emission wavelength, such minor differences can result from the limitations when making such spectroscopic measurements, i.e., differences in the calibration of the spectrophotometer, deviations in absorptivity coefficients at high concentrations (>0.01M) due to electrostatic interactions between molecules in close proximity, scattering of light due to particulates in the sample fluorescence or phosphorescence of the sample, changes in refractive index at high analyte concentration, shifts in chemical equilibria as a function of concentration, non-monochromatic radiation, deviations can be minimized by using a relatively flat part of the absorption spectrum such as the maximum of an absorption band, and stray light. Equally important is the fact that both proteins fluorescence in the yellow color range which is 570-590 nm, and the yellow observed by the naked eye is indistinguishable whether it is 578 nm or 583 nm. With regard to the limitation of "pH sensitivity of light-absorbing properties," most common buffer for dissolving proteins when making such spectroscopic measurements is water

Art Unit: 1656

which has pH of ~7, and as mentioned before, all proteins have a light-absorbing property. As such, the pH sensitivity of light-absorbing properties of DsRed is stable between pH 4 and 10. With regard to the recitation of "molar absorption coefficient is 61,150," it is unclear because there is no unit designation following the number "61,150." As such, there is no way of knowing what the number represents, and therefore, it is not considered as one of the claimed limitations. Likewise, the recitation, "quantum yield is less than 0.01," is not considered as one of the claimed limitations because such measurements of quantum yield vary depending on the solvent system used to dissolve the proteins, i.e., water, PBS, methanol, ethanol, cyclohexane, 0.1 M NaOH and 0.1M H<sub>2</sub>SO<sub>4</sub>. Thus, the properties of DsRed read on the claimed limitation. Therefore, the reference of Wall et al. anticipates Applicants' claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wall et al. (The structural basis for red fluorescence in the tetrameric GFP homolog DsRed, *Nature Structural Biology*, 2000, 7(12): 1133-1138).

The teachings of Wall et al. are as described above. The reference of Wall et al. does not explicitly state the use of the transparent plastic tubes for handling/manipulating the DNA.

It is noted by the Examiner that the recitation of "kit" in claim 10 broadly encompasses a transparent plastic tube that contains a solution with DNA and/or protein.

It would have been obvious to one of ordinary skill in the art to make and use a kit comprising at least one of (1) the chromoprotein of claim 1, (2) a DNA encoding the protein, (3) a transformant having the DNA or the recombinant vector, or (4) a fusion protein composed of the chromoprotein and another protein as (1), (2) and (3) are taught by the reference of Wall et al., because one of skill in the art would put the DNA dissolved solution in the transparent plastic tubes for cloning, subcloning and/or amplification while inserting said DNA into a His<sub>6</sub>-tagged expression vector, pRSET<sub>B</sub> in order to express the protein encoded by said DNA (see pg. 1137 under "Methods: protein purification and crystallization"). One would have been motivated to make and use such kits because storing DNA inside said tubes keep said DNA from being contaminated and degraded by exogenous agents while manipulating. One would have had a reasonable expectation of success to make and use the claimed kit comprising said DNA, at least to the extent required by the instant claims, because the use of transparent tubes to store/manipulate various DNA expression vectors were known and practiced rampantly in the field at the time of filing.



### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-7 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-12, 14, 15 and 18 of copending Application No. 10/516,317. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a DNA encoding an amino acid sequence, which comprises a deletion, substitution and/or addition of one or several amino acids with respect to the amino acid sequence shown in SEQ ID NO: 1, and has light-absorbing properties (see attached nucleic acid sequence alignment of SEQ ID NO: 2 from both applications, which encode the amino acid sequence as set forth in SEQ ID NO: 1) and both claims are supported by almost identical specifications.

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

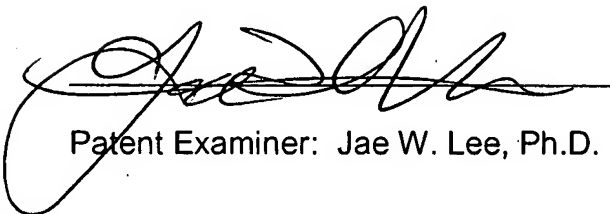
Claims 3-7 and 10 are rejected for the reasons as stated above. Applicants must respond to the objections/rejections in this Office action to be fully responsive in prosecution.

The instant Office action is non-final.

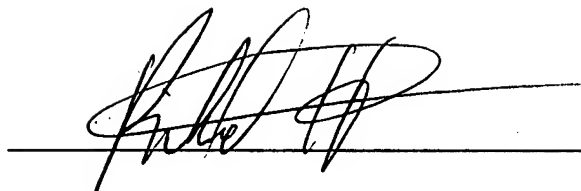
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Patent Examiner: Jae W. Lee, Ph.D.



**RICHARD HUTSON, PH.D.**  
**PRIMARY EXAMINER**